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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,431	07/18/2003	Jay D. Kranzler	CYPR 100 CIP CON	4067

23579 7590 09/29/2004

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EXAMINER	
COOK, REBECCA	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,431	KRANZLER ET AL.	
	Examiner	Art Unit	
	Rebecca Cook	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/18/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 53 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from cancelled claim 24. For the purpose of compact prosecution claim 53 will be examined as if it depended from claim 52. Claim 55 will be examined as if it depended from claim 54.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/26623.

'623 discloses (abstract) that milnacipran, an SNRI, is used to treat CFS and FMS and symptoms associated therewith. Said symptoms include pain.

It would be obvious to one of ordinary skill in the art to use milnacipran to treat FMS, CFS and pain, since '623 discloses that it is used to treat CFS, FMS and symptoms associated therewith, which include pain.

The dependent claims differ over the reference in reciting a second compound, and reciting dosage and dosage formulation. However, the instant "comprising" language does not exclude a second compound. Furthermore, once a method of using a compound is known, it is within the skill of the artisan to optimize the method. This would include the exclusion or inclusion of additional compounds and dosage and dosage formulations.

Claims 50-55 differ over the references in reciting a kit with instructions. Dependent claims 51, 53 and 55 recite unit dosage packaging. However, the inclusion of a package insert "teaching a method of use" of a pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art when the composition is known in the art. Furthermore, no unobviousness is seen in unit dose packaging, which is routine in the pharmaceutical art.

Claims 335-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over DRUGU AN 1992-39596 (Moreau et al) in view of DRUGU AN 1983-01770 (Woerz zum Thema). Moreau discloses that antidepressants are used to treat pain. The instant claims differ over Morreau in reciting the use of a SNRI to treat pain. However, Woerz zum Thema (abstract) discloses that milnacipran, an SNRI, is an antidepressant agent. It would be obvious to one of ordinary skill in the art to use milnacipran to treat pain and yield the instant method, since Moreau discloses that antidepressants are used to treat pain and Woerz zum Thema discloses that milnacipran is an antidepressant agent.

Dependent claims recite drug regimens and dosages. However, once a method of use is known it is within the skill of the artisan to determine the optimum regimen and

dosage. Furthermore, Woerz zum Thema discloses that the neuroleptics and opiates are also used to treat pain. In the absence of a showing of unexpected results commensurate in scope with the claims no unobviousness is seen in using neuroleptics and opiates with milnacipran, since each is taught by the art to be useful to treat pain. Moreover, optimization is also within the skill of the art absence unexpected demonstrated results.

Claims 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over EMBASE AN 1998129084 or EMBASE AN 90228858.

'084 (abstract) and '858 (abstract) each disclose a composition comprising milnacipran, an SNRI. '084 discloses that it is used in both ambulatory and hospital settings. '858 discloses that it is used in hospitalized patients.

Claims 50, 52 and 54 differ over the references in reciting a kit with instructions. Dependent claims 51, 53, and 55 recite unit dosage packaging. However, the inclusion of a package insert "teaching a method of use" of the pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. Furthermore, no unobviousness is seen in unit dose packaging, which is routine in the pharmaceutical art, especially in an institutionalized setting such as the ones disclosed by '084 and '858.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,602,911. Although the conflicting claims are not identical, they are not patentably distinct from each other because '911 recites a method of treating symptoms of FMS, which include pain, using milnacipran, an SNRI. This renders obvious the instant method of treating FMS, its symptoms and pain.

Claims 35-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,635,675. Although the conflicting claims are not identical, they are not patentably distinct from each other because '675 recites a method of treating symptoms of CFS, including pain, with milnacipran, an SNRI. This renders obvious the instant method of treating CFS, its symptoms and pain.

Claims 26-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-16 and 24-25 of copending Application No. 10/623,378. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treating pain using milnacipran, an SNRI and its kit, render obvious the instant method

treating pain associated with MS and CFS, as well as general pain, using an SNRI, which includes milnacipran and its kit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Information Disclosure Statement

The following references were not present in the parent files and could not be considered: EP 0 759299, FR 2 752732, WO 97/35584, WO 99/59593, WO 00/32178, WO 02/053140, Dwight, Goodnick, Medline, Ninan, Nutt & Johnson and Rao.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

Rebecca Cook

Primary Examiner
Art Unit 1614

September 27, 2004